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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,185	03/07/2001	Jochen G. Salfeld	BBI-043CPUSCN	1672

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,185	SALFELD ET AL.	
	Examiner	Art Unit	
	David A Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74-142* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *74-142* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/28/04 has been entered.

Following entry of this submission, claims 74-142 are pending and under examination.

1) Claims 88, 101, 103, 120 and 139 are objected to because of the following informalities:

Claims 88 and 103 end with both a comma (after "Iloprost") and a period.

Claims 101, 120 and 139 end without a period.

Appropriate correction is required.

2) The amendment has overcome previously stated rejection(s) under 35 USC 112, second paragraph.

New grounds of rejection under 112, second para. follow:

Claims 88, 91-98, 103, 106-113 and 122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 88, line 1 "any one of claims 84" should read as –claim 84--. The Markush group of claim 88 is improper because there is no –and-- before the last member.

In claims 91, 93, 95, and 97, line 1 of each, "any one of claims 84" should read as –claim 84--.

In claim 103, line 1 "any one of claims 99" should read as –claim 99--. The Markush group of claim 103 is improper because there is no –and-- before the last member.

In claims 106, 108, 110 and 112, line 1 of each, "any one of claims 99" should read as –claim 99--.

In claim 122, line 1 "the additional therapeutic agent" lacks antecedent basis.

3) The amendment has overcome previously stated rejection(s) under 35 USC 112, first paragraph, except for the rejection of claims 88 and 103 maintained as follows:

Claims 88 and 103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter for reasons of record.

To further explain, with particular reference to claim 88 (as presented in the amendment of 3/17/03), it is noted that the agents listed from "non-steroidal anti-inflammatory drugs" (line 2) through "azaribine" (line 18) were derived from spec. page 29, line 28–page 31, line 12; these describe the treatment of rheumatoid arthritis. The agents listed from "budenoside" (line 18) through "lignocaine" (line 25) were derived from spec. page 31, lines 13-30; these describe treatment of inflammatory bowel disease. Agents listed form "prednisoline" (line 25) through "clarabine" (line 27) were derived from spec. page 31, line 31-page 32, line 1; these describe treatment of MS. Agents listed from "hypertonic saline solutions" (line 27) through "Synthetic Anti-Endotoxin Peptides" (line 32) were derived from spec. page 32, lines 7-27; these describe treatment of sepsis. The agents "surfactant replacement therapy and anti-IL-8 antibodies" (lines 32-33) were derived from spec. page 33, line 30; these describe treatment of ARDS.

Applicant's arguments filed 6/28/04 have been fully considered but they are not persuasive. Applicant has urged that these listings of additional therapeutic agents were intended as merely exemplary of the more broad disclosures at spec. page 29, lines 14-24 and page 33, lines 1-2. The examiner's position is that these teachings merely support the broad recitation in base claim 74, which has not been rejected as containing new matter.

The examiner's position is that claim 88 (as presented 3/17/03) recites a new subgenus of treatments that are not supported. The examiner does concur that some of the agents recited in claim 88 were listed for the treatment of more than one disease. For example, "IL-4" is listed for the treatment of rheumatoid arthritis (page 30, line 5), inflammatory bowel disease (page 31, line 25), and MS (page 32, line 5); but IL-4 was not disclosed for the treatment of other discussed diseases at pages 29-32. By not limiting the nature of the disease being treated, applicant is extending the scope of the disclosed treatments using the subject anti-TNF-alpha antibody and IL-4 to new and unspecified types of disease. This is new matter, just as the case would be, in a more simple example, if applicant had originally disclosed a specific organic compound and a specific pharmaceutical carrier and their use specifically for the treatment of hypertension and then wanted to extend the scope of the treatment method to other diseases.

Regarding claim 88 (as amended on 6/28/04), the examiner maintains that this recites new matter. This claim has now been limited to recite a subset of the agents listed at page 29, line 28+ for the treatment of rheumatoid arthritis. Following the rational supra, this claim contains new matter by not being limited to treatment of rheumatoid arthritis.

The rejection of claim 103, which was presented on 3/17/03 and amended on 6/28/04 in the same manner as for claim 83, is likewise maintained.

4) New grounds of rejection under 112, first paragraph follow:

Claims 122-127 and 129-133 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims recite new matter, following the same rational set forth supra for claims 88 and 103.

Claim 122 is recited with a Markush group of additional agents; this group is essentially like that presented in claim 88 on 3/17/03. As noted in the above review of claim 88, these agents were listed as pertaining to the treatment of certain diseases listed at spec. pages 29-32. None of the diseases contemplated at pages 29-32 included "periodontal disease, obesity, and radiation toxicity", which are the diseases recited in base claim 118 and which would be treated in the method of dependent claim 122. Applicant has thus improperly extended the originally disclosed treatment method to a new group of diseases.

Claims 123 and 129 recite a Markush Group of additional agents which are disclosed at spec. page 29, line 28-page 31, line 12 for the treatment of the disease rheumatoid arthritis. Since claims 123 and 129 are not limited to treatment of rheumatoid arthritis, applicant has improperly extended the scope of the originally disclosed treatment method.

Claims 124 and 129 recite a Markush Group of additional agents which are disclosed at spec. page 30, lines14-28 for the treatment of the disease rheumatoid arthritis. Since claims 124 and 129 are not limited to treatment of rheumatoid arthritis, applicant has improperly extended the scope of the originally disclosed treatment method.

Claims 125 and 131 recite a Markush Group of additional agents which are disclosed at spec. page 30, line 33-page 31, line 12 for the treatment of the disease rheumatoid arthritis. Since claims 125 and 131 are not limited to treatment of rheumatoid arthritis, applicant has improperly extended the scope of the originally disclosed treatment method.

Claims 126 and 132 recite a curious Markush Group of additional agents. Those listed through "azaribine" (at line 3) are disclosed at spec. page 31, lines 11-12 for the treatment of the disease rheumatoid arthritis. Those listed after "azaribine" are disclosed at spec. page 31, lines 13-30 for the treatment of inflammatory bowel disease. Since claims 126 and 132 are not limited to treatment of rheumatoid arthritis for the agent members listed through "azaribine" and are not limited to treatment of inflammatory bowel disease for the agents listed after "azaribine", applicant has improperly extended the scope of the originally disclosed treatment method.

Claims 127 and 133 recite a curious Markush Group of additional agents. Those listed through "claribine" (line 4) are disclosed at spec. page 31, line 33-page 32, line 1 for the treatment of MS. Those listed through "Synthetic Anti-Endotoxin Peptides" (line 9) are disclosed at spec. page 32, lines 7-27 for the treatment of sepsis. The "surfactant replacement therapy and anti IL-8 antibodies" (lines 9-10) are disclosed at spec. page 32, line 30 for the treatment of ARDS. Since claims 127 and 133 are not limited to treatment of MS for the agent members listed through "clarabine" and are not limited to treatment of sepsis for the agents listed through "synthetic Anti-Endotoxin Peptides", and are not limited to treatment of ARDS for the agents "surfactant replacement therapy and anti IL-8 antibodies", applicant has improperly extended the scope of the originally disclosed treatment method.

Claims 83, 90, 105, 122, 124 and 130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In these claims the Markush group member "corticosteroids" is broader than what was originally disclosed as "corticosteroid anti-inflammatory drugs" (pg 30, line 32).

5) Double patenting rejections are maintained as follows:

Claims 74-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 24-25 and 28 of U.S. Patent No. 6,090,382. Although the conflicting claims are not identical, they are not patentably distinct from each other. See reasons in action of 5/29/03 at page 6.

Claims 74 and 83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 24-25 of U.S. Patent No. 6,090,382 in view of Aggarwal et al. See reasons in action of 5/29/03 at page 6; note, for example, "corticosteroids" is recited in both the reference and in claim 83.

Claims 84-87, 89, 91, 93, 95, 97, 99-102, 104, 106, 108, 110, 112, 135 and 138-140 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 15, 17, 22, 36-39, 69, 87 and 93 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other. See reasons in action of 5/29/03 at pages 6-7. New claims 135 and 138-140 have limitations included in claims previously rejected and are thus added to this ground of rejection.

Claims 84-87, 89-91, 93-97, 99-102, 104-106, 108-112, 123-125, 127-131, 133-134 and 136-137 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 15, 17, 22, 36-39, 87, and 93 of U.S. Patent No. 6,509,015 in view of Aggarwal et al. See reasons in action of 5/29/03 at page 7. Due to the amendment of claims 88 and 103, their rejection on this ground has been dropped. New claims 123-125, 127-131, 133-134, and136-137 recite agents in common with those taught by Aggarwal et al (e.g. gold, corticosteroids, methlypredinisolone, cyclosporin, antibiotics) and are thus added to the rejection.

Claims 84-88, 91-92, 98-103, 106-107, 112-113, 126, 132 and 141-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 36-39 and 69 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons stated in the action of 5/29/03 at page 8 regarding the use of the recited additional therapeutic agents. Amended claims 88 and 103, as well as new claims 126, 132 and 141-142, have been added to this ground of rejection.

Claims 114-121 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons in action of 5/29/03 at page 8.

Claims 118 and 122 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 36 and 69 of U.S. Patent No. 6,509,015 in view of Aggarwal et al. Claim118 has been rejected according to the paragraph above. Issued

claim 69 shows use of an additional therapeutic agent and Aggarwal et al teach additional agents that are among those of claim 122.

6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0849. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 8/19/04 DAS

David A Saunders

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PRIMARY EXAMINER
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